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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/029,424	12/20/2001	Thomas W. Leonard	8789-24	3706
20792	7590	07/28/2004	EXAMINER	
MYERS BIGEL SIBLEY & SAJOVEC			KIM, JENNIFER M	
PO BOX 37428			ART UNIT	PAPER NUMBER
RALEIGH, NC 27627			1617	

DATE MAILED: 07/28/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>
	10/029,424	LEONARD ET AL.
Examiner	Art Unit	
Jennifer Kim	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

1)  Responsive to communication(s) filed on 30 April 2004.

2a)  This action is **FINAL**.                            2b)  This action is non-final.

3)  Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

4)  Claim(s) 32, 34 and 35 is/are pending in the application.  
4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5)  Claim(s) \_\_\_\_\_ is/are allowed.

6)  Claim(s) 32, 34 and 35 is/are rejected.

7)  Claim(s) \_\_\_\_\_ is/are objected to.

8)  Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

9)  The specification is objected to by the Examiner.

10)  The drawing(s) filed on \_\_\_\_\_ is/are: a)  accepted or b)  objected to by the Examiner.

    Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

    Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)  The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)  Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a)  All b)  Some \* c)  None of:  
1.  Certified copies of the priority documents have been received.  
2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3.  Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1)  Notice of References Cited (PTO-892)  
2)  Notice of Draftsperson's Patent Drawing Review (PTO-948)  
3)  Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date

4)  Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_ .

5)  Notice of Informal Patent Application (PTO-152)

6)  Other: \_\_\_\_\_

## **DETAILED ACTION**

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on April 30, 2004 has been entered.

The rejection of claim 32 of record under 35 U.S.C. 103 (a) over KAKEN of record in view of Borah et al. of record is withdrawn in view of the newly acquired English machine transulations enclosed herein.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claim 32 is rejected under 35 U.S.C. 102(b) as being anticipated by KAKEN PHARM CO LTD (KAKEN) (English transulation).

KAKEN teaches the composition comprising the connected-together type (conjugated) estrogen including estrone and 17 $\beta$ -estradiol combined with therapeutically effective amounts of an androgen including oxandrolone, oxymetholone and stanozolol with starch or polyethyleneglycol etc. (pharmaceutical carriers). (claims 1-3, page 14, lines 5-20, page 16, lines 1-17, [0010], [0019], page 25-27, Examples).

Claim 34 rejected under 35 U.S.C. 102(e) as being anticipated by Martin et al. (WO/74684A1) of record.

Martin et al. teach Applicants' pharmaceutical formulation including a pharmaceutically acceptable carrier and the combinations of active ingredients of (i) an therapeutically effective amount of androgen such as oxymetholone, oxandrolone and stanozolol, (ii) an estrogen such as estrogenic compound including conjugated estrogen

and sodium salts of sulfate esters of conjugates of estrogens such as estrone and 17 $\beta$  estradiol and (iii) a progestin. (page 9, lines 9-14, pages 6-8, page 14, lines 20-33).

Claim 35 is rejected under 35 U.S.C. 102(b) as being anticipated by Huber et al. (U.S. Patent No. 5,908,638).

Huber et al. teach a pharmaceutical composition containing conjugated estrogen in combination with effective amount of progestogen and excipients. (abstract, Examples). Huber et al. teach the conjugated estrogens includes the sodium sulfate esters of estrone, equilin, 17 $\alpha$  dihydroequilin, 17 $\beta$  dihydroequilin and 17 $\alpha$  estradiol. (columns 15 and 16, claims 1-14).

### **Response to Arguments**

Applicant's arguments filed on April 30, 2004 have been fully considered but they are not persuasive. Applicants argue KAKEN fails to teach or suggest the use of a non-aromatizing androgen with an estrogenic compound, therefore there is no motivation to produce the pharmaceutical formulation as recited in independent claim 32. This is not persuasive because KAKEN (English translation enclosed herein) teaches the composition comprising the connected-together type (conjugated) estrogen including estrone and 17 $\beta$ -estradiol combined with an androgen including oxandrolone, oxymetholone and stanozolol with starch or polyethyleneglycol etc. (pharmaceutical carriers). Therefore, the teaching fully meets Applicants' claiming invention of claim 32.

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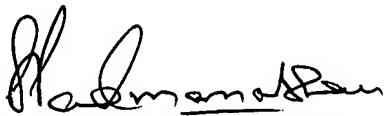
Thus, the claims fail to patentably distinguish over the state of the art as represented by the cited references.

None of the claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer Kim whose telephone number is 571-272-0628. The examiner can normally be reached on Monday through Friday 6:30 am to 3 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Sreenivasan Padmanabhan  
Supervisory Examiner  
Art Unit 1617

Jmk

July 6, 2004